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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,785	09/12/2003	Joern Moeckel	2924-216	5867

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ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K STREET, N.W.
SUITE 800
WASHINGTON, DC 20005

EXAMINER	
SPEAR, JAMES M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,785	MOECKEL ET AL.	
	Examiner	Art Unit	
	James M. Spear	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER
AU 1615

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/7/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Terminal Disclaimer filed 23 March 2005 has been received and approved. The Information Disclosure Statement filed 07 February 2005 has been entered. After further review and consideration it has been determined that the following new grounds of rejection are necessary.

1. The disclosure is objected to because of the following informalities:

Minor spelling errors are noted: Claim 36, line 5, derivates or derivatives?, claim 39, line 3, trimelliatate or trimellitate, claim 41, line 6, should be release

Appropriate correction is required.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-37, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Canadian pat. 2,093,946. See examples 1, 3 and 4. Example 4 shows the particular drug ibandronate. The formulations which may include tablets are utilized in methods for treating conditions such as osteoporosis, Paget's disease and hypercalcemia. See page 1, paragraph 1, page 6, paragraphs 1-3, page 8, lines 11-22. The examples further show particular cellulose coatings equivalent to those of applicants'. The release rates would inherently be the same as applicants' because the formulation components are the same as applicants'.

3. Claims 21-37, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Canadian Patent 2,149,052. See Abstract, claims 23, 31, 34, and 37, page 4 line 32 through page 5, line 2, page 6, lines 19-22. The reference shows ibandronate coated tablets wherein cellulose polymers such as hydroxypropylcellulose comprise the coating. The tablets would inherently have the same release rates and properties as applicants' because the tablet ingredients are the same.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 21-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canadian Patent 2,149,052 in view of EP 0 421 921 A1 and Canadian Pat 1,305,166.

The '052 patent shows methods of treating bone disease using coated ibandronate tablets as explained above. The reference does not show the particular polymethacrylate coatings of applicants' claims 38 and 39. The reference shows tablets wherein the dose of ibandronate may be from 50 mg to 1 gm. The '166 patent teaches methods of treating bone disease using adjustable dosing wherein multiple dosing or once daily dosing is used to administer amounts of 1 to 1000 mg. ibandronate. See page 1, last 2 paragraphs, page 7, lines 3-6 and 24-28. It is well known in the art that in order to administer large doses of a drug modified release coatings are used such as the polymethacrylate polymers. The EP 0 421 921 A1 reference is relied on for teaching enteric coatings, such as the EUDRAGITS, applied to diphosphonic acid dosage forms. See the examples.

7. It would have been obvious to one of ordinary skill in the art to tailor the administration of ibandronate as taught by the '166 reference adjusting the dosing and use the modified release polymethacrylate coatings of the EP reference to administer large dose of ibandronate of the '052 patent when desired. The motivation being a desire to provide optimum therapeutic effect with minimal side effects. Depending on the dosage regimen whether it is designed to provide sustained or controlled release or release in a site specific area of the GI tract such dosing using said coatings would increase patient compliance because the number of required doses would be reduced and the patient would experience less possible side effects.

Claims 21-41 are rejected.

Claims 1-20 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

James M Spear
Primary Examiner
Art Unit 1618

29 April 2005